REMARKS

The Applicant appreciates the Examiner's favorable consideration of claims 13-34 and 64-67. Claim 1, 5, 35 and 58 have been amended. No claims have been added or deleted. Accordingly, with the entry of this amendment, claims 1, 5-35, 42-50, 52, 58-59 and 64-67 will be pending.

Independent Claim 1 and Dependent Claims 6-12

Claims 1 and 8 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,555,885 issued to Chance ("Chance") and U.S. Patent No. 6,081,612 issued to Gutkowicz-Krusin ("Gutkowicz-Krusin"). Claims 6 and 7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Gutkowicz-Krusin in view of Chance in view of U.S. Patent No. 5,355,880 issued to Thomas ("Thomas"). Claim 11 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Gutkowicz-Krusin in view of Chance and further in view of U.S. Patent No. 5,726,276 issued to Lemelson ("Lemelson"). Claim 12 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Gutkowicz-Krusin in view of Chance, Thomas and Lemelson.

Claim 1 has been amended as set forth above. Support for the amendment can be found, *inter alia*, on the complete paragraph of page 44 and claim 13 (pages 5 and 6).

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicant respectfully asserts that a *prima facie* case of obviousness has not been established. First, there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Moreover, Applicant respectfully submits that one of ordinary skill in the are would likely not reasonably expect such a combination to succeed even if suggestion or motivation existed. Furthermore, even assuming *arguendo* that the references are somehow combinable and that a reasonable expectation of success exists in combining the two, the combination still does not teach or suggest, among other things, using

a portion of the data generated in analyzing the remitted light to normalise a further portion of the data.

More particularly, both Gutkowicz-Krusin and Chance rely on a direct measure of a parameter. Gutkowicz-Krusin discloses the use of acquiring images of tissue taken using various spectra of light between 400nm and 1000nm. These images are then input into a statistical analysis that is used to determine whether the skin has malignancy. There is no discussion of normalizing the data against a portion of the data before analysis is made. Chance relies upon time resolved spectral analysis of breast tissue. Fluorescence is also used to assist in a diagnosis. Again, there is no discussion of normalizing the data against a portion of the data before analysis is made.

The normalization process allows a histological parameter, which may not be the final desired parameter, to be measured as a first step. This measurement is then used to normalize the spectral information so as to allow another parameter to be measured. Thus, the method allows a parameter to be measured that is not directly measurable from the light remitted from the illuminated area.

Accordingly, Applicant again respectfully submits that a *prima facie* case of obviousness has not been established. Reconsideration and allowance of claim 1 are therefore respectfully requested.

Claims 6-12 depend from allowable claim 1, and are therefore allowable. Moreover, claims 6-12 may contain additional patentable subject matter for reasons that may or may not be set forth herein. Reconsideration and allowance of claims 6-12 are respectfully requested.

Independent Claim 5

Claim 5 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Chance and Gutkowicz-Krusin.

Applicant respectfully asserts that a *prima facie* case of obviousness has not been established with respect to claim 5. First, there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Moreover, Applicant respectfully submits that one of ordinary skill in the are would likely not reasonably expect such a combination to succeed even if suggestion or motivation existed. Furthermore, even assuming *arguendo* that the references are somehow combinable and that a reasonable expectation of success exists in combining the two, the combination still does not teach or suggest, among other things,

spectroscopically analyzing the remitted light in order to generate data indicative of the remitted light, using a portion of the data to normalize a further portion of the data and comparing variations in the intensity and spectral characteristics of the remitted light of the normalized further portion of data with respect to the intensity and spectral characteristics of the projected light and with data representing a datum sample of intensity and spectral characteristics of light remitted by a sample of tissue of know structure.

For the same and similar reasons set forth above with respect to claim 1, Chance and Gutkowicz-Krusin, taken separately or combined, do not teach or suggest the subject matter of claim 5. More particularly, both Gutkowicz-Krusin and Chance rely on a direct measure of a parameter. Gutkowicz-Krusin discloses the use of acquiring images of tissue taken using various spectra of light between 400nm and 1000nm. These images are then input into a statistical analysis that is used to determine whether the skin has malignancy. There is no discussion of normalizing the data against a portion of the data before analysis is made. Chance relies upon time resolved spectral analysis of breast tissue. Fluorescence is also used to assist in a diagnosis. Again, there is no discussion of normalizing the data against a portion of the data before analysis is made.

Accordingly, Applicant again submits that a *prima facie* case of obviousness has not been established. Reconsideration and allowance of claim 5 are therefore respectfully requested.

Independent Claim 13 and Dependent Claims 14-33

The Examiner's allowance of claims 13-33 is appreciated.

Independent Claim 34

The Examiner's allowance of claim 34 is appreciated.

Independent Claim 35 and Dependent Claims 42-50 and 52

Claims 35, 42-49 and 52 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Chance and Gutkowicz-Krusin. Claim 50 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Chance and Gutkowicz-Krusin, and further in view of Lemelson.

Applicant respectfully asserts that a *prima facie* case of obviousness has not been established with respect to claim 35. First, there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Moreover, Applicant

respectfully submits that one of ordinary skill in the are would likely not reasonably expect such a combination to succeed even if suggestion or motivation existed. Furthermore, even assuming *arguendo* that the references are somehow combinable and that a reasonable expectation of success exists in combining the two, the combination still does not teach or suggest, among other things, an apparatus comprising

a light source for projecting light to illuminate an area of such tissue sample,

a photo receptor for receiving light remitted by the illuminated area of tissue, and a spectroscopic analyzer for monitoring the remitted light and for generating data indicative of the remitted light,

a processor arranged to use a portion of the data to normalize a further portion of the data, and

a comparator for comparing variations in the intensity and spectral characteristics of the remitted light of the normalized further portion of the data with respect to the intensity and spectral characteristics of the projected light at different wavelengths and with data representing a datum sample of intensity and spectral characteristics of light remitted by a reference sample of known structure and a signal emitter for emitting a control signal in response to any such variations.

For the same and similar reasons set forth above with respect to claims 1 and 5, Chance and Gutkowicz-Krusin, taken separately or combined, do not teach or suggest the subject matter of claim 35. More particularly, both Gutkowicz-Krusin and Chance rely on a direct measure of a parameter. Gutkowicz-Krusin disclose the use of acquiring images of tissue taken using various spectra of light between 400nm and 1000nm. These images are then input into a statistical analysis that is used to determine whether the skin has malignancy. There is no discussion of normalizing the data against a portion of the data before analysis is made. Chance relies upon time resolved spectral analysis of breast tissue. Fluorescence is also used to assist in a diagnosis. Again, there is no discussion of normalizing the data against a portion of the data before analysis is made.

Accordingly, Applicant again submits that a *prima facie* case of obviousness has not been established. Reconsideration and allowance of claim 35 are therefore respectfully requested.

Claims 42-50 and 52 depend from allowable claim 35, and are therefore allowable. Moreover, claims 42-50 and 52 may contain additional patentable subject matter for reasons that may or may not be set forth herein. Reconsideration and allowance of claims 42-50 and 52 are respectfully requested.

Independent Claim 58 and Dependent Claim 59

Claims 58 and 59 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Gutkowicz-Krusin in view of Thomas.

Applicant respectfully asserts that a *prima facie* case of obviousness has not been established. First, there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Moreover, Applicant respectfully submits that one of ordinary skill in the are would likely not reasonably expect such a combination to succeed even if suggestion or motivation existed. Furthermore, even assuming *arguendo* that the references are somehow combinable and that a reasonable expectation of success exists in combining the two, the combination still does not teach or suggest a method of analyzing biological tissue comprising illuminating the tissue with light, spectrally measuring and analyzing the differences between the incident and remitted light, the analysis of this data to define a parameter of the tissue, the use of a portion of the data to normalize a further portion of the data to a standard value of that parameter using a predictive mathematical model of the optical properties of the biological tissue, and the subsequent measurement of a further parameter form that normalized data.

More particularly, Gutkowicz-Krusin relies on a direct measure of a parameter. Gutkowicz-Krusin disclose the use of acquiring images of tissue taken using various spectra of light between 400nm and 1000nm. These images are then input into a statistical analysis that is used to determine whether the skin has malignancy. There is no discussion of normalizing the data against a portion of the data before analysis is made. Thomas does not cure this deficiency.

Accordingly, Applicant again submits that a *prima facie* case of obviousness has not been established. Reconsideration and allowance of claim 58 are therefore respectfully requested.

Claim 59 depends from allowable claim 58, and is therefore allowable. Moreover, claim 58 may contain additional patentable subject matter for reasons that may or may not be set forth herein. Reconsideration and allowance of claim 59 are respectfully requested.

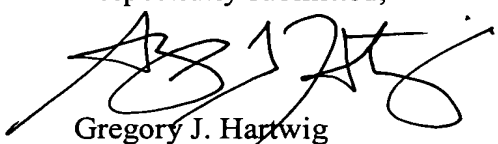
Independent Claims 66-67

The Examiner's allowance of claims 64-67 is appreciated.

CONCLUSION

In view of the foregoing, reconsideration and allowance of the application are respectfully requested. Should any issues remain, the Examiner is strongly encouraged to contact the undersigned by telephone.

Respectfully submitted,



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